REMARKS

The Amendments

Claim 1 is amended to clarify that the active agent in the formulation administered according to the invention "consists of" the therapeutically effective amount of a salt of tiotropium. Thus, the method is distinguished by excluding administration of other active substances. Applicants intended for the previous claims to make this distinction. However, the Final office action indicates that a different interpretation was taken. Thus, the claims are amended to make the distinction more clear. Support for the amendment is found throughout the specification. For example, see all of the examples and specifically described embodiments wherein the only active agent is a tiotropium salt. See also, page 2, third and fourth paragraphs, page 4, last paragraph, and page 10, first full paragraph.

The amendments do not narrow the broadest scope of the claims and/or are not made for purposes of patentability.

It is submitted that the above amendments would put the application in condition for allowance or materially reduce or simplify the issues for appeal. The amendments do not raise new issues or present new matter and do not present additional claims. The amendments have been made merely to clarify applicants' intended meaning of the claims, i.e., that all other active agents are excluded. This intent is believed to have been met by the previous claims and was made clear in applicants' previous arguments, thus, a new issue is not being raised. The claim amendment is made to avoid the alternative interpretation taken in the Final action. Thus, the amendment was not earlier presented. Accordingly, it is submitted that the requested amendment

should be entered.

Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

The Rejection under 35 U.S.C. §102

The rejection of claims 9, 11-23 and 25-32 under 35 U.S.C. §102, as being anticipated by Pairet (US Pub. No. 2002/0122773), is respectfully traversed.

Pairet requires the combination of two active substances, i.e., an anticholinergic and a dopamine agonist; see, e.g., the Summary of the Invention (page 1, para. 0002), page 1, paras. 0007-0009, and all of the examples. Pairet, therefore, does not disclose and anticipate a method which "comprises administering, via inhalation, a formulation wherein the active substance consists of a therapeutically effective amount of a salt of tiotropium, and, optionally, physiologically acceptable excipients." The "consists of" language in claim 9 excludes from the claimed method embodiments wherein the salt of tiotropium is administered in combination with another active substance. Thus, it excludes the Pairet method requiring the additional dopamine agonist active substance.

The position taken in the Office action is that, since the claim also recites the open "comprises" language in the broader aspect – i.e., "comprises administering, via inhalation, a formulation wherein the active substance consists of a therapeutically effective amount of a salt of tiotropium, and, optionally, physiologically acceptable excipients" – the claim does read on the addition of other active agents. Applicants respectfully disagree with such interpretation and

believe the relevant case law and patent practice stated in the MPEP support their interpretation. The case law on claim interpretation is clear that, within an open language claim, certain components or elements of the invention may be limited by the use of more restrictive terms, such as "consists of," see, e.g., Mannesmann Demag Corp. v. Engineered Metal Products, Co., Inc., 230 USPQ 45 (Fed. Cir. 1986); and, Berenter v. Quigg, 14 USPQ 2d 1175 (D.C. Dist. Ct. 1988). See also, MPEP §2111.03, stating: "When the phrase 'consists of' appears in a clause of the body of a claim, rather than immediately following the preamble, it limits only the element set forth in that clause; other elements are not excluded from the claim as a whole," and also citing the Mannesmann Demag decision. Thus, while the initial "comprises" term in the claim provides open language on terms which are not otherwise specified in the claim, the claim is restricted by the "consists of" term as to the active substance being administered. Thus, the claims do not encompass the embodiments disclosed by Pairet wherein the additional active substance, dopamine agonist, is administered. It is clear from Pairet and the general knowledge in the art that a dopamine agonist is an active substance in such a method.

Accordingly, Pairet does not anticipate the claimed invention and the rejection under 35 U.S.C. §102 should be withdrawn.

Applicants also point out that Pairet is excluded from application as prior art for obviousness purposes in view of 35 U.S.C. §103(c). Applicants hereby state that the subject matter described in Pairet and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person. Thus, Pairet cannot be applied as prior art for obviousness purposes under 35 U.S.C. §102(e)/103.

It is submitted that the application is in condition for allowance. But the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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